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1. Introduction

The purpose of this document is to support a process to evaluate whether the registered uses of methomyl (PC code 090301) will result in potential risk to endangered and threatened (listed) species and/or designated critical habitat. This effort is being completed in support of the registration review process. In registration review, all pesticides distributed and sold in the United States are reevaluated every 15 years to make sure that as changes occur, products in the marketplace can still be used safely without unreasonable adverse effects[1] to non-listed species under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and that registered uses do not jeopardize the continued existence of listed species and/or result in adverse modification of critical habitat as administered under the Endangered Species Act (ESA).

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1.1.1. Nature of the Regulatory Action

1.1.1.1. Pesticide registration

Pursuant to FIFRA, before a pesticide product may be sold or distributed in the U.S., it must be exempted or registered with a label identifying approved uses by EPA's Office of Pesticide Programs (OPP). Pesticide registration is the process through which EPA examines the ingredients of a pesticide; the site or crop on which it is to be used; the amount, frequency and timing of its use; and storage and disposal practices. Pesticide products (also referred to as "formulated products") may include active ingredients (a.i.s) and other ingredients, such as adjuvants and surfactants. EPA authorization of pesticide uses are categorized as FIFRA Sections 3 (new product registrations), 18 (emergency use), or 24(c) Special Local Needs (SLN).

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[redacted] Pesticides must be registered or exempted by EPA before they may be sold or distributed in the U.S. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide's label or labeling.

After registering a pesticide, EPA retains discretionary involvement and control over such registration. EPA must periodically review the registration to ensure compliance with FIFRA and other federal laws (7 U.S.C. §136d). A pesticide registration can be cancelled whenever "a pesticide or its labeling or other material…does not comply with the provisions of FIFRA or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." For details on pesticide cancellation procedures under FIFRA 6(f), please see the following link:

https://www.epa.gov/pesticide-tolerances/pesticide-cancellation-under-epas-own-initiative

"Restricted" pesticides may be applied only by or under the direct supervision of specially trained and certified applicators (40 CFR 171). Certification and training programs are conducted by states, territories, and tribes in accordance with national standards.

Methomyl was first registered as an insecticide in 1968. [redacted]

1.1.1.2. Registration review

In 2006, EPA initiated a new program called registration review to reevaluate all pesticides on a regular cycle. EPA is required to review each pesticide active ingredient at least every 15 years to make sure that as the ability to assess risks to human health and the environment evolves and as policies and practices change, all pesticide products in the marketplace can still be used safely. Registration review includes Sections 3, 24(c), and 18 labels.

1.1.1.3. Pesticide labels

The label on a pesticide package or container is legally enforceable. The label provides information about how to handle and safely use the pesticide product and avoid harm to human health and the environment. Using a pesticide in a manner that is inconsistent with the use directions on the label is a violation of FIFRA and can result in enforcement actions to correct the violations.

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1.1.1.4. Monitoring and reporting

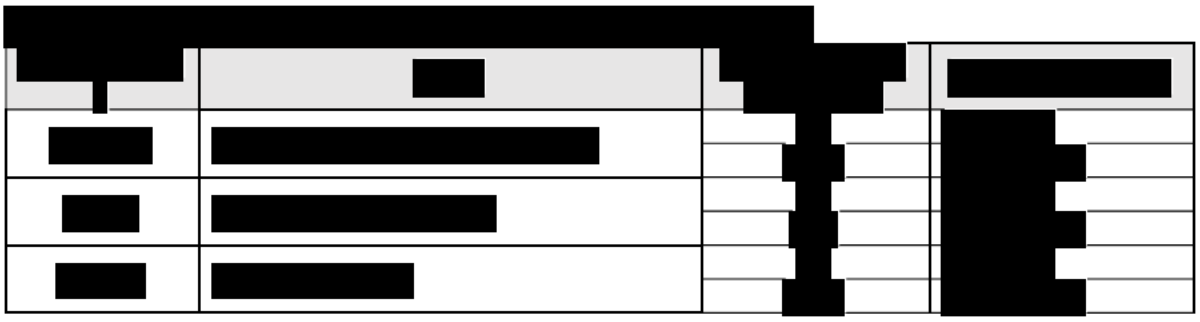
The current Federal Action does not include any specific provision for monitoring. However, Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act requires pesticide product registrants to report adverse effects information, such as incident data (**ATTACHMENT 1-1**), about their products to the EPA. Several regulations and guidance documents have been published which provide registrants and the public with details on what, when and how to report this information. For more information, see the following website: https://www.epa.gov/pesticide-incidents/incident-reporting-pesticide-manufacturers-registrants

1.1.2. Use Data (Labels)

1.1.2.1. Current registrations

Methomyl is a carbamate insecticide used on a wide variety of terrestrial food and feed crops, terrestrial non-food crops, and non-agricultural indoor and outdoor sites. There are currently 3 active technical registrants of methomyl with 34 active product labels (16 Section 3s and 18 Special Local Needs), which include formulated products and technical grade methomyl [redacted] All of the formulated methomyl products, with the exceptions of the fly bait products are Restricted Use Pesticides (RUPs) – meaning that they can only be applied by, or under the supervision of, a certified applicator. Methomyl can be applied in a liquid, granular (corn only), scatterbait, bait station, or as a brush-on paste. Aerial and ground application methods (including broadcast, soil incorporation, orchard airblast, and chemigation) are allowed. [redacted] Registered labels for granular products require a 25-foot (ground) buffer zone adjacent to waterbodies.

Currently, there are 3 multi-active ingredient products registered that contain methomyl. The only other active ingredient co-formulated with methomyl is the insect sex pheromone Z-9-tricosene [PC code 103201 ((Z)- isomer)] in the fly bait products. [redacted]



1.1.2.2. Inert ingredients

An inert ingredient is any substance (or group of structurally similar substances if designated by the Agency), other than an "active" ingredient, which is intentionally included in a pesticide product. It is important to note, the term "inert" does not imply that the chemical is nontoxic.

Inert ingredients play a key role in the effectiveness of a pesticidal product. Pesticide products may contain more than one inert ingredient; however, federal law does not require that these ingredients be identified by name or percentage on the label. All inert ingredients in pesticide products, including those in an inert mixture, must be approved for use by the EPA. For those inert ingredients applied to food crops, a tolerance or tolerance exemption is required. Impurities are not included in the definition of inert ingredient. As part of the review process for all new ingredients, a screening-level ecological effects hazard assessment is conducted, in which available data on the toxicity of the inert ingredient to non-target organisms is considered.

For the most current list of inert ingredients approved for food use pesticide products, see the Electronic Code of Federal Regulations (e-CFR) at http://www.ecfr.gov/cgi-bin/text-idx?SID=26b254e3ec275241162fb666aa219c7b&mc=true&node=pt40.24.180&rgn=div5. The majority of inert ingredients can be found in 40 CFR 180.910-180.960. Forty CFR part 180 also contains a number of sections that include tolerances/ tolerance exemptions[4] for specific inert ingredients where their use is usually significantly limited. The listing of nonfood use inert ingredients, including those that also have food uses, can be found in InertFinder[5].

[4] See http://www.epa.gov/pesticides/factsheets/stprf.htm for details on what tolerances and tolerance exemptions are.

[5] InertFinder is an online database for searching substances used as inert ingredients in pesticide products. It can be found at: http://iaspub.epa.gov/apex/pesticides/f?p=101:1:

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1.1.2.4.a. Summary of non-agricultural uses

All non-agricultural and non-orchard, outdoor uses for methomyl are limited to turf (sod farm only) and fly baits that can be used around livestock animal and poultry premises, commercial structures and commercial dumpsters (that are enclosed). The fly baits can be used as a perimeter scatterbait, placed in bait stations (hung at least 4 feet high), or mixed with water to form a paste which can be brushed onto walls, window sills, and support beams of livestock houses (outside). [redacted]

1.1.2.4.b. Summary of agricultural uses

Methomyl is currently registered on a variety of agricultural use sites, including: alfalfa, anise (fennel), apple, asparagus, avocado, bean (dry and succulent), beet, bermudagrass pasture, blueberry, broccoli, brussel sprouts, cabbage, carrot, cauliflower, celery, chicory, chinse cabbage, collards, corn (field, pop-corn, seed and sweet corn), cotton, cucumber, eggplant, endive (escarole), garlic, grapefruit, horseradish, leafy green vegetables, lemon, lentils, lettuce (head and leaf), melon, potato, sorghum, soybean, spinach, sugar beet, summer squash, tangelo (tangerine)tobacco, tomato, tomatillo and wheat. In addition, there are several special local need (SLN) use sites, including broccoli raab, chinese broccoli, bean and soybean inter-planted with non-bearing fruit and nut trees, pumpkin, and sweet potato for California and radish for California and Florida. [redacted]

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1.2. Pesticide Active Ingredient Information

1.2.1. Mode and Mechanism of Action

Methomyl is an N-methylcarbamate insecticide. Carbamate insecticides act by inhibiting acetylcholinesterase, thereby reducing the degradation of the cholinergic neurotransmitter acetylcholine. As a result, intersynaptic concentrations of acetylcholine increase as the neurotransmitter accumulates leading to increased firing of the postsynaptic neurons. This may ultimately lead to convulsions, paralysis, and death of an organism exposed to the chemical. Acetylcholinesterase inhibition is rapidly reversed in many taxa once exposure to an N-methylcarbamate insecticide has ended.

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